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## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

USGINZ002110

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on June 2, 2009

Signature

Typed or printed name Quyen Nguyen

Application Number

10/612,109

Filed

July 1, 2003

First Named Inventor

Richard C. EWERS

Art Unit

3761

Examiner

Melanie Jo Hand

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐

applicant/inventor.

☐

assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)

☒

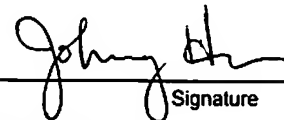
attorney or agent of record.

Registration number 45, 565

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attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 \_\_\_\_\_



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June 2, 2009

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

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\*Total of 1 of 1 forms are submitted.

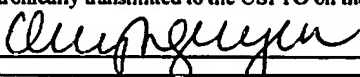
This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Date: June 2, 2009

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 (Quyen Nguyen)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application No.: 10/612,109  
Confirmation No.: 3376  
Filing Date: July 1, 2003  
Inventor(s): Richard C. EWERS et al.  
Title: DELIVERY SYSTEMS AND METHODS FOR  
GASTRIC REDUCTION  
Examiner: Hand, Melanie Jo  
Group Art Unit: 3761

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**REASONS SUPPORTING PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This is in response to the Final Office Action mailed January 2, 2009 ("the 1/2/09 Final Office Action"), in the above-identified United States Patent Application. Filed herewith is a Notice of Appeal and fee, and a petition and fee for a two month extension of time. Accordingly, this response is timely filed. A pre-appeal brief review is requested for the reasons set forth below.

**INTRODUCTION**

The present application relates generally to a delivery catheter used to manipulate tissue and deliver a tissue anchor into tissue. The catheter is particularly adapted for use in a gastric reduction system to form and maintain tissue folds endoluminally, e.g., via a catheter that is inserted through a patient's mouth and esophagus and into the patient's stomach.

For example, embodiments of the delivery catheter are shown in FIGS. 12 and 15A-B, which are reproduced below. The catheter 11 includes an elongated flexible tube having a lumen and a needle 16 disposed for translation through the lumen. A push rod translates within a lumen of the needle to eject an anchor 22 out of the distal end of the

delivery catheter. In the FIG. 15A embodiment, a coil screw 24 having a sharpened tip 25 is mounted to a distal end of the delivery catheter.

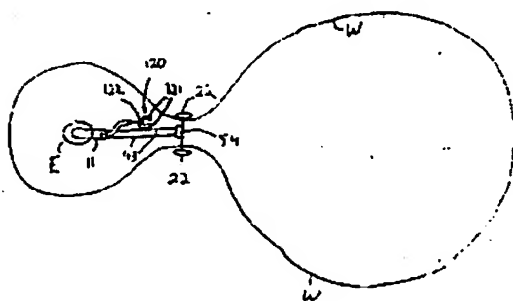


FIG. 12

In the FIG. 15B embodiment, the coil screw 24 is formed on the distal end of a shaft that is translatable through a separate lumen 135 of the flexible tube.

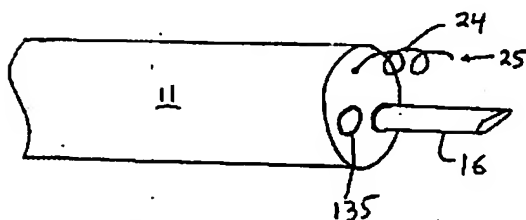


FIG. 15A

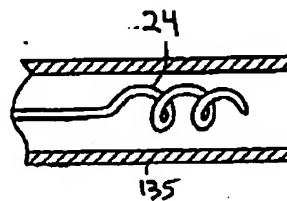


FIG. 15B

During operation, the delivery catheter is inserted through a patient's mouth and esophagus E, and into the stomach S. (See, e.g., FIG. 12). The coil screw 24 is engaged to the tissue wall W to stabilize the distal end of the delivery catheter and to facilitate penetration of the needle 16 into the tissue wall W. Then, a push rod ejects the anchor(s) 22 out of the distal end of the delivery catheter and through the tissue wall W. The anchor(s) 22 are attached to one or more sutures 43 that are used to maintain the tissue in a reconfigured state.

### **ISSUES ON APPEAL**

At issue is whether the following claims should be rejected under 35 U.S.C. § 103 for obviousness over the following combinations of references: (a) claims 1, 9, 10, 12, 46, 51-53, 55, and 58-60 over U.S. Patent Pub. No. 2003/0167071 to Martin et al. ("Martin") in view of U.S. Pat. No. 6,656,182 to Hayhurst ("Hayhurst"); (b) claims 2, 3, 5, 47, and 48 over the combination of Martin and Hayhurst, in further view of U.S. Patent Pub. No. 2002/058905 to Madrid et al. ("Madrid"); (c) claims 8 and 49 over the combination of Martin and Hayhurst, in further view of U.S. Patent Pub. No. 2003/0208211 to Kortenbach

("Kortenbach"); (d) claim 54 over the combination of Martin and Hayhurst, in further view of U.S. Patent Pub. No. 2002/0087098 to Iwami et al. ("Iwami"); and (e) claim 56 over the combination of Martin and Hayhurst, in further view of U.S. Patent No. 6,921,378 to O'Keefe ("O'Keefe"). Appellant has argued that none of the foregoing combinations teaches all of the elements of the claims, and that it would not have been obvious to combine several of references in the manner proposed. The Examiner has found all of Appellant's arguments to be non-persuasive.

### **ARGUMENT**

The 1/2/09 Final Office Action rejects all of the pending claims for obviousness based upon the five combinations of references set forth above. These rejections are identical to rejections set forth in a prior non-final office action mailed May 16, 2008 ("the 5/16/08 Nonfinal Office Action"). Applicant traversed those rejections, without amending the claims, in a response filed October 16, 2008 ("Applicant's 10/16/08 Response"). *Applicant directs the attention of the Reviewers to Applicant's 10/16/08 Response and incorporates by reference herein the Remarks included at pages 9-13 of that response.*

The 1/2/09 Final Office Action includes a section (at pages 2-4) entitled "Response to Arguments," in which the Examiner presents counter-arguments to those included in Applicant's 10/16/08 Response. Respectfully, Applicant submits that the arguments set forth in Applicant's Remarks contained in Applicant's 10/16/08 Response were sufficient to traverse the rejections, and that the purported responses contained in the 1/2/09 Final Office Action do not change this result.

#### **I. Rejections Over Martin in view of Hayhurst**

In Sections A.1 and A.2 of Applicant's 10/16/08 Response, spanning pages 9-11, Applicant explained that the combination of Martin and Hayhurst does not support the claim rejections set forth in the Office Action because: (1) the proposed combination does not disclose or teach all of the limitations recited in the claims, and (2) the proposed combination would not have been obvious to a person skilled in the art. Specifically, contrary to the contentions stated in the 1/2/09 Final Office Action, the Martin publication does not teach or disclose "a coil on a front end of a shaft that is translatably disposed within a lumen" in the flexible tube. This feature is recited in each of the pending independent claims – claims 1, 46, 55, 59, and 60. On the contrary, the Martin "coil 250" is one of the described forms of the "fastening element 102." (Martin, paragraph 0060). Nowhere does the Martin

publication describe or teach that the coil 250 (or fastening element 102) is “on a front end of a shaft” or that such shaft is “translatably disposed within a lumen” of the flexible tube (i.e., the “loading tool 200”). In addition, the Hayhurst patent does not correct the deficiencies of the Martin publication. Finally, for the reasons stated in section A.2 of Applicant’s prior response, the Office Action fails to state a legitimate reason for combining the Martin and Hayhurst references. In fact, there are several reasons why a person skilled in the art would not combine these references in the manner proposed.

For a more full explanation of these points, Applicant directs the Reviewers’ attention to the Remarks contained in Sections A.1 and A.2 of Applicant’s 10/16/08 Response.

The “Response to Arguments” set forth in the 1/2/09 Final Office Action do not address, much less contradict, the claim rejection traversals stated in Applicant’s prior response. For example, nowhere does the Response state that Martin shows “a coil on a front end of a shaft that is translatably disposed within a lumen.” Nor does the Response provide a legitimate reason for combining these references in the manner proposed.

For these reasons, Applicant submits that the rejections of claims 1, 9, 10, 12, 46, 51-53, 55, and 58-60 cannot be supported, and must be withdrawn.

## **II. Rejections Over Martin and Hayhurst in view of Other Art**

In Sections B-E of Applicant’s 10/16/08 Response, spanning pages 11-13, Applicant explained that the combinations of Martin and Hayhurst with Madrid (claims 2, 3, 5, 47, and 48), Kortenbach (claims 8 and 49), Iwami (claim 54), and O’Keefe (claim 56) do not support the claim rejections set forth in the Office Action because the proposed combinations do not disclose or teach all of the limitations recited in the claims. Specifically, none of the Madrid, Kortenbach, Iwami, and O’Keefe references corrects the deficiencies of the combination of Martin and Hayhurst discussed in Section I above. In addition, as reasonably interpreted, the Madrid tubular body 46 braided layer (Madrid, paragraph 0046) does not meet the recited limitation that “the tube contains a plurality of slots disposed substantially perpendicular to a longitudinal axis of the tube.” In addition, the Office Action fails to state a legitimate reason for combining either of the Kortenbach or O’Keefe references with the combination of Martin and Hayhurst.

For a more full explanation of these points, Applicant directs the Reviewers’ attention to the Remarks contained in Sections B through E of Applicant’s 10/16/08 Response.

The "Response to Arguments" set forth in the 1/2/09 Final Office Action do not contradict these traversals of the claim rejections. For example, the contention that the Madrid braid strands will "change their angle" ignores the fact that these "braid strands" are embedded in or on the wall of the tubular body 26, meaning that there is no "tube [that] contains a plurality of slots" as recited in claims 3 and 48. Nor does the Response provide a legitimate reason for combining the references in the manner proposed.

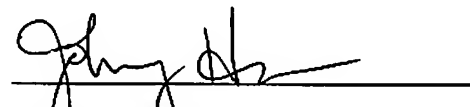
For these reasons, Applicant submits that the rejections of claims 2, 3, 5, 8, 47-49, 54, and 56 cannot be supported, and must be withdrawn.

**CONCLUSION**

In view of the foregoing, the Application is in condition for allowance. The rejections of the pending claims set forth in the Final Office Action should be withdrawn and the claims passed to issue.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **USGINZ02110**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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